

II. CLAIMS

1. (Currently Amended) Diagnostic procedure for identification of a disorder of ~~a pancreas~~ pancreatic function in a patient comprising determining an overall content of ~~all known~~ pancreatic elastases I, II and III (iso-enzymes) in the patient's serum, secretions or excretions by

a) administering two or more of the following synthetic peptides to the patient

NH2-A-V-K-E-G-P-E-Q-V-I-P-I-N-COOH (SEQ ID NO: 2)

NH2-Y-T-N-G-P-L-P-D-K-L-Q-Q-A-R-COOH (SEQ ID NO: 3)

NH2-R-S-G-C-N-G-D-S-G-G-P-L-N-COOH (SEQ ID NO: 5)

NH2-G-P-L-N-C-P-T-E-D-G-G-W-Q-COOH (SEQ ID NO: 4)

NH2-G-T-E-A-G-R-N-S-W-P-S-Q-I-COOH (SEQ ID NO: 6)

NH2-H-N-L-S-Q-N-D-G-T-E-Q-Y-V-COOH (SEQ ID NO: 7)

NH2-W-G-K-T-K-T-N-G-Q-L-A-COOH (SEQ ID NO: 8)

NH2-V-S-S-R-G-C-N-V-S-R-K-P-T-COOH (SEQ ID NO: 9)

NH2-G-G-E-E-A-R-P-N-S-W-P-W-Q-COOH (SEQ ID NO: 10)

NH2-S-S-S-R-T-Y-R-V-G-L-G-R-H-N-COOH (SEQ ID NO: 11)

NH2-K-D-W-N-S-N-Q-I-S-K-G-N-D-COOH (SEQ ID NO: 12)

NH2-G-P-L-N-C-Q-A-S-D-G-R-W-COOH (SEQ ID NO: 13)

NH2-G-A-L-P-D-D-L-K-Q-G-R-L-COOH (SEQ ID NO: 14)

NH2-S-L-Q-Y-E-K-S-G-S-F-Y-COOH (SEQ ID NO: 15)

NH2-F-G-C-N-T-R-R-K-P-T-V-F-T-COOH (SEQ ID NO: 16)

to induce antibodies which ~~immuno-chemical systems using monoclonal or polyclonal antibodies, being single specific antibodies or cross-reactive antibodies that can recognize~~ pancreatic elastases I, II or III (iso-enzymes) but which cannot recognize an elastase fragment with the amino-acid sequence Thr-Met-Val-Ala-Gly-Gly-Asp-Ile-Arg (SEQ ID NO: 1), and

b) detecting the existence of and quantifying antigen-antibody reactions with the elastases.

2. Cancelled

3. (Currently Amended) The procedure according to claim 1, comprising obtaining antibodies by ~~means~~

a) immunizing a animal selected from rabbits, guinea pigs, goats, chickens and fish with antigens selected from the group consisting of complete elastases 1, 2 and 3 and of their sub-units wherein the amino-acid sequence Thr-Met-Val-Ala-Gly-Gly-Asp-Ile-Arg (SEQ ID NO: 1) is not used as an elastase fragment or as an immunologically effective partial sequence thereof;

b) separating and purifying the formed antibodies, thereby obtaining monoclonal and/or polyclonal antibodies that react specifically with human elastase 1, 2 and 3 in stool or body fluids.

4- 5. Cancelled

6. (Currently Amended) Immunological test kits for a diagnosis and progress check of diseases of the pancreas of a patient using stool or body fluids containing one or more of monoclonal or polyclonal antibodies, where the antibodies are single specific antibodies or cross-reactive antibodies that can recognize ~~all~~ elastase iso-enzymes 1, 2 and 3 but not the amino-acid sequence Thr-Met-Val-Ala-Gly-Gly-Asp-Ile-Arg (SEQ ID NO: 1).

7. (Currently Amended) Procedure for obtaining monoclonal and/or polyclonal antibodies that react specifically with human elastase 1 in stool or body fluids and are induced by immunization procedures, comprising administering peptides

A-V-K-E-G-P-E-Q-V-I-P-I-N (SEQ ID NO: 2),

Y-T-N-G-P-L-P-D-K-L-Q-Q-A-R (SEQ ID NO: 3),

R-S-G-C-N-G-D-S-G-G-P-L-N (SEQ ID NO: 5) and

G-P-L-N-C-P-T-E-D-G-G-W-Q (SEQ ID NO: 4) or immunogenic portions of these peptides to a vertebrate,

inducing the formation of antibodies, and

separating and purifying the formed antibodies,

thereby obtaining monoclonal and/or polyclonal antibodies that react specifically with human elastase 1 in stool or body fluids.

8. (Previously Presented) The procedure according to claim 7, comprising coupling peptides with carrier substances before administration to the vertebrate.

9. (Previously Presented) The procedure according to claim 7, wherein the vertebrate is a chicken.

10. (Previously Presented) The procedure of claim 7 where the antibodies are polyclonal antibodies.

11. (Previously Presented) The procedure of claim 7 where the antibodies are monoclonal antibodies.

12. (Previously Presented) Synthetic peptide A-V-K-E-G-P-E-Q-V-I-P-I-N (SEQ ID NO: 2).

13. (Previously Presented) Synthetic peptide Y-T-N-G-P-L-P-D-K-L-Q-Q-A-R (SEQ ID NO: 3).

14. (Previously Presented) Synthetic peptide R-S-G-C-N-G-D-S-G-G-P-L-N (SEQ ID NO: 5).

15. (Previously Presented) Synthetic peptide G-P-L-N-C-P-T-E-D-G-G-W-Q (SEQ ID NO: 4).

16. Cancelled

17. (Currently Amended) Immunological test kits for diagnosis and progress check of diseases of a pancreas and of mucoviscidosis using stool or body fluids comprising antibodies induced by administering to an patient synthetic peptides selected from the group consisting of:

NH₂-A-V-K-E-G-P-E-Q-V-I-P-I-N-COOH (SEQ ID NO: 2)
NH₂-Y-T-N-G-P-L-P-D-K-L-Q-Q-A-R-COOH (SEQ ID NO: 3)
NH₂-R-S-G-C-N-G-D-S-G-G-P-L-N-COOH (SEQ ID NO: 5)
NH₂-G-P-L-N-C-P-T-E-D-G-G-W-Q-COOH (SEQ ID NO: 4)
NH₂-G-T-E-A-G-R-N-S-W-P-S-Q-I-COOH (SEQ ID NO: 6)
NH₂-H-N-L-S-Q-N-D-G-T-E-Q-Y-V-COOH (SEQ ID NO: 7)
NH₂-W-G-K-T-K-T-N-G-Q-L-A-COOH (SEQ ID NO: 8)
NH₂-V-S-S-R-G-C-N-V-S-R-K-P-T-COOH (SEQ ID NO: 9)
NH₂-G-G-E-E-A-R-P-N-S-W-P-W-Q-COOH (SEQ ID NO: 10)
NH₂-S-S-S-R-T-Y-R-V-G-L-G-R-H-N-COOH (SEQ ID NO: 11)
NH₂-K-D-W-N-S-N-Q-I-S-K-G-N-D-COOH (SEQ ID NO: 12)
NH₂-G-P-L-N-C-Q-A-S-D-G-R-W-COOH (SEQ ID NO: 13)
NH₂-G-A-L-P-D-D-L-K-Q-G-R-L-COOH (SEQ ID NO: 14)
NH₂-S-L-Q-Y-E-K-S-G-S-F-Y-COOH (SEQ ID NO: 15) and
NH₂-F-G-C-N-T-R-R-K-P-T-V-F-T-COOH (SEQ ID NO: 16)

which antibodies are bound to a carrier and cross-reactively recognize several elastases but which cannot recognize the amino-acid sequence Thr-Met-Val-Ala-Gly-Gly-Asp-Ile-Arg (SEQ ID NO: 1).

18. (Previously Presented) Immunological test kits according to claim 17, wherein 2 different antibodies are used and the test kit is a Sandwich-ELISA test kit.

19. (Previously Presented) The procedure of claim 8 where the immunization procedure comprises coupling peptides to

hemocyanin.

20. (Previously Presented) The procedure according to claim 3 where synthetic peptides are used as antigens for induction of B-cells which are fused with myeloma cells for generating hybridoma cells which are cultivated in cell lines producing specific monoclonal antibodies.

21. (Previously Presented) The procedure of claim 1 where the antibodies are polyclonal antibodies.

22. (Previously Presented) The procedure of claim 7 where the antibodies are polyclonal antibodies.

23. (New) The diagnostic procedure of claim 1 in which the pancreatic elastase is pancreatic elastase I and the synthetic peptide administered is selected from

NH₂-A-V-K-E-G-P-E-Q-V-I-P-I-N-COOH (SEQ ID NO: 2),
NH₂-Y-T-N-G-P-L-P-D-K-L-Q-Q-A-R-COOH (SEQ ID NO: 3),
NH₂-R-S-G-C-N-G-D-S-G-G-P-L-N-COOH (SEQ ID NO: 5),
NH₂-G-P-L-N-C-P-T-E-D-G-G-W-Q-COOH (SEQ ID NO: 4).

23. (New) The diagnostic procedure of claim 1 in which the pancreatic elastase is pancreatic elastase II or elastase III.